REMARKS

I. Introduction

In response to the Office Action dated May 24, 2007, claims 1, 24, 35, 58, and 107 have been amended and claims 5, 27, 39 and 62 have been cancelled. Claims 1, 2, 4, 9-25, 30-37, 43-59, 64-68 and 107 remain in the application. Re-examination and re-consideration of the application, as amended, is requested.

II. Claim Amendments

Applicants' attorney has made amendments to the claims as indicated above. These amendments focus the claims on embodiments of the invention relating to medical infusion tubing used to deliver a fluid and treat a physiological condition. Dependent claims 5, 27, 39 and 62 have been correspondingly cancelled. In addition, all independent claims have been amended to explicitly recite embodiments of the invention directed to medical infusion tubing having dimensions permitting the infusion of insulin in a fluid from the infusion device through the medical infusion tubing to an individual having the physiological condition as well as a fitting adapted to connect to an infusion device.

The amendments to the claims are fully supported by the specification as filed and introduce no new matter. Infusion pump devices and systems designed to deliver insulin are described for example in paragraph [0002]. The disclosure in paragraph [00025] teaches that those of skill in the art use medical tubing of various dimensions depending upon the medication and it required delivery rate. Illustrative dimensions etc. for tubing used with insulin infusion devices is shown for example in Figures 1A and 1B.

III. Examiner Interview Summary

Record is made of telephone interviews on October 18, 2007 and October 24, 2007 between Applicants' attorney William Wood, and Examiner Koharski in connection with the present patent application. Applicants' attorney sincerely thanks Examiner Koharski for his helpful comments and suggestions.

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IV. Prior Art Rejections

On pages (2)-(3) of the Office Action, claims 1, 2, 4, 5, 13, 14, 17-20, 22-25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62 and 65-68 were rejected under 35 U.S.C. §102 as being anticipated by Dugmore, WO 00/56384 (Dugmore). On page (3) of the Office Action, claims 1, 24, 35, 58 and 107 were rejected under 35 U.S.C. §102 as being anticipated by Novosel, U.S. Patent 5,975,120 (Novosel). On pages (3)-(5) of the Office Action, claims 9-11, 15, 43-45 and 49 were rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Dugmore and Peterson, U.S. Publication 2003/0098067 (Peterson). On page (5) of the Office Action, claims 12, 16, 21, 46, 50, 55 and 64 were rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Dugmore and Novosel.

In the sections below, Applicant's attorney reviews the cited references and the invention recited in the claims as amended hereinabove. Applicant's attorney then illustrates why those of skill in this art would not agree that the subject matter recited in the claims as amended hereinabove is anticipated and/or rendered obvious by the various disclosures cited by the Patent Office.

1. THE CITED REFERENCES AND THE SUBJECT INVENTION

THE DUGMORE REFERENCE

Dugmore, WO 00/56384 teaches an adjustable and retractable needle assembly designed to withdraw blood from a patient. The invention disclosed in Dugmore is constructed to protect phlebotomists from needle sticks by having an adjustable needle assembly comprising a needle housing, a first needle guide passage defined in a front end of the housing, a needle that is axially slidable within the passage, and needle length adjusting means, wherein the guide passage defines a central guide axis, and the needle length adjusting means is arranged to deviate the needle laterally relative to the guide axis to adjust the distance that the needle projects from the housing.

As described for example in the first full paragraph bridging pages 8 and 9 and shown in Figures 1-12, this apparatus for withdrawing blood from an individual includes a fluid conduit in the form of a needle having a first sharp front end that functions to pierce the skin of the individual to withdraw blood from a vein. As also described first full paragraph bridging pages 8 and 9 and shown in Figures 1-12, this fluid conduit in the form of a needle further includes a second sharp

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back end that functions to pierce the stopper of a vacuum phial. When the phlebotomist uses the first end of the needle to pierce the skin and the second end of the needle to pierce the phial stopper, the resulting direct communication with the vacuum chamber defined within the phial results in blood being drawn from the vein into the phial via the needle.

THE NOVOSEL REFERENCE

Novosel, U.S. Patent 5,975,120 teaches an automatically retractable gas feeding spool to be used as an accessory for use with individuals who must rely on oxygen therapy (see, e.g. the field of the invention). As noted in the abstract, this gas feeding spool provides a means of automatically dispensing air tubing on demand of the user in order to assist breathing, then retracting it, upon signal by the user.

THE PETERSON REFERENCE

Peterson, U.S. Publication 2003/0098067 teaches a gas tubing reel includes a housing having a tubing-reel rotatably positioned therein for unwinding and retracting tubing. The tubing-reel is biased in a retracting direction and includes ratcheting and releasing means for selectably paying out or retracting the tubing. A swivel housing is coupled to the tubing-reel in a bearing relationship and includes an inlet port for receiving an end of the tubing and an outlet port for coupling to a nasal cannula. Thus, a gas may be delivered from a gas source through the gas tubing, swivel coupling, and cannula to a patient without tangling or twisting the tubing.

THE SUBJECT INVENTION

All independent claim have been amended hereinabove to focus on those embodiments of the invention that dispense medical infusion tubing of the kind used to used to deliver insulin to treat diabetes. Medical infusion tubing used with insulin infusion devices must exhibit the (small) dimensions that allow the slow infusion of insulin over a long period of time (see e.g. FIG. 1A and FIG. 1B). Moreover, such medical infusion tubing is required by health regulatory agencies (e.g. the F.D.A.) to be made from materials that do not degrade when exposed to compounds present in therapeutic fluids, for example the phenolic preservatives used in therapeutic insulin formulations. In addition, all independent claims now recite embodiments of the invention that dispense medical

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tubing having a fitting adapted to connect to an infusion device, wherein the fitting is not for piercing an organ of the individual.

2. APPLICANTS' RESPONSE TO THE REJECTION TO CLAIMS 1, 2, 4, 5, 13, 14, 17-20, 22-25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62 AND 65-68 UNDER 35 U.S.C. §102(b)

On page (2) of the Office Action, claims 1, 2, 4, 5, 13, 14, 17-20, 22-25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62 and 65-68 were rejected under 35 U.S.C. §102(b) as being anticipated by Dugmore, WO 00/56384 (Dugmore). Applicants respectfully traverse this rejection.

As noted above, all pending claims have been focused on those embodiments of Applicants' invention the include "medical infusion tubing having a fitting adapted to connect to an infusion device and dimensions permitting the infusion of insulin in a fluid from the infusion device through the medical infusion tubing to an individual having the physiological condition, wherein the fitting is not for piercing an organ of the individual". The Dugmore reference cannot anticipate these amended claims because Dugmore teaches conduits with ends that have sharp needle structures, ones specifically designed to pierce an organ (e.g. a vein) for the collection of blood. The Dugmore reference consequently fails to teach or suggest an apparatus that includes medical infusion tubing having a fitting adapted to connect to an infusion device that is not for piercing an organ of the individual because tubing having this structure would destroy the operability of the Dugmore invention (e.g. by making it impossible to pierce a patient's skin during blood collection).

As noted in M.P.E.P. 2131, to anticipate a claim, a reference must teach every element of a claim. In particular, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single art reference. Because the Dugmore disclosure fails to teach or suggest medical infusion tubing having the fitting as recited in the amended claims, much less medical infusion tubing having dimensions permitting the infusion of insulin in a fluid from an infusion device, this disclosure cannot anticipate the claimed invention. For this reason, Applicants respectfully request a withdrawal of the rejection to claims 1, 2, 4, 5, 13, 14, 17-20, 22-25, 27, 30-37, 39, 47, 48, 51-54, 56-59, 62 and 65-68 were rejected under 35 U.S.C. §102(b) as being anticipated by Dugmore.

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2. APPLICANTS' RESPONSE TO THE REJECTION TO CLAIMS 1, 24, 35, 58 AND 107 UNDER 35 U.S.C. §102(b)

On page (3) of the Office Action, claims 1, 24, 35, 58 and 107 were rejected under 35 U.S.C. §102 as being anticipated by Novosel, U.S. Patent 5,975,120 (Novosel). Applicants respectfully traverse this rejection.

As noted above, all pending claims have been focused on those embodiments of Applicants' invention the include "medical infusion tubing having a fitting adapted to connect to an infusion device and tubing dimensions permitting the infusion of insulin in a fluid from the infusion device through the medical infusion tubing to an individual having the physiological condition". As noted above, such medical infusion tubing is comprised from materials designed to resist degradation by compounds present in therapeutic fluids such phenolic preservatives (e.g. as found in therapeutic insulin formulations). Moreover, the medical infusion tubing used with insulin infusion devices further exhibits the (small) dimensions that allow the slow infusion of insulin over a long period of time (see e.g. FIG. 1A and FIG. 1B).

The Novosel reference cannot anticipate claims as amended hereinabove because this reference fails to teach or suggest medical infusion tubing, much less devices to be used with such tubing. Instead, Novosel teaches devices designed to dispense air tubing to people who must rely on oxygen therapy. Because Novosel teaches an apparatus used to deliver a breathable gas (i.e. oxygen) and not a fluid, it provides no teaching whatsoever regarding tubing designed to deliver fluids, much less medical infusion tubing having a blunt end adapted to connect to an infusion device and dimensions permitting the infusion of insulin.

As noted in M.P.E.P. 2131, to anticipate a claim, a reference must teach every element of a claim. In particular, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single art reference. Because the Novosel disclosure fails to teach or suggest any medical infusion tubing, much less medical infusion tubing having a blunt end adapted to connect to an infusion device and/or having dimensions permitting the infusion of insulin in a fluid from an infusion device, this disclosure cannot anticipate the claimed invention. For this reason, Applicants respectfully request a withdrawal of the rejection to claims 1, 24, 35, 58 and 107 were rejected under 35 U.S.C. §102(b) as being anticipated by Novosel.

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3. APPLICANTS' RESPONSE TO THE REJECTION TO CLAIMS 9-12, 15, 16, 21, 43-46, 49, 50, 55 and 64 UNDER 35 U.S.C. §103(a)

On pages (3)-(5) of the Office Action, claims 9-11, 15, 43-45 and 49 were rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Dugmore and Peterson, U.S. Publication 2003/0098067 (Peterson).

On page (5) of the Office Action, claims 12, 16, 21, 46, 50, 55 and 64 were rejected under 35 U.S.C. §103(a) as being obvious in view of the combination of Dugmore and Novosel.

Applicants respectfully traverse these rejections under 35 U.S.C. §103(a) because the all independent claims as amended hereinabove recite embodiments of the invention that include medical infusion tubing having a fitting adapted to connect to an infusion device and further recite that this fitting element is not for piercing an organ of the individual As noted above, because Dugmore teaches needle assembly designed to withdraw blood from a patient, the end of Dugmore's flexible conduit is a sharp needle that is specifically designed to pierce an organ (e.g. the skin) of a patient and obtain access to a vein for blood withdrawal. Because the Dugmore apparatus requires these sharp needle ends to function properly, one of skill in the art would have no motivation to substitute and/or modify this disclosure to generate Applicants' apparatus including tubing designed to have the fitting recited in the amended claims. In particular, M.P.E.P. § 2143.03 explicitly notes that if a proposed modification would render the prior art invention unsatisfactory for its intended purpose, then there can be no suggestion or motivation to make the proposed modification.

In addition, one of skill in the art would note that medical infusion tubing having the fitting recited in the claims as amended hereinabove cannot operate as does the needle disclosed in Dugmore, one which is designed to pierce the skin of a patient and obtain access to a vein for blood withdrawal. In such situations, courts hold that "If when combined, the references 'would produce a seemingly inoperative device,' then they teach away from their combination." *In re Gurley*, 27 F.3d 551, 553, 31 U.S.P.Q.2d 1130 (Fed. Cir. 1994). Because the Dugmore apparatus could not operate if the sharp stiff needles Dugmore teaches are used to pierce flesh and draw blood were substituted with the fitting recited in the amended claims, this disclosure teaches away from the invention recited in the amended claims.

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As noted above, Dugmore teaches away from devices designed to dispense the infusion tubing and fitting as recited in the amended claims. As noted in M.P.E.P. 2145(D)(2), references cannot be combined where a reference teaches away from their combination. For this reason, the Dugmore reference cannot be combined with the Peterson reference in order to render the invention recited in claims 9-11, 15, 43-45 and 49 obvious. For the same reason, the Dugmore reference cannot be combined with the Novosel reference in order to render the invention recited in claims 12, 16, 21, 46, 50, 55 and 64 obvious. For this reason, Applicants respectfully request a withdrawal of the rejections under 35 U.S.C. 103(a).

Moreover, the various elements of Applicants' claimed invention together provide operational advantages over Dugmore, Novosel and Peterson. In addition, Applicants' invention solves problems not recognized by Dugmore, Novosel and Peterson.

Thus, Applicants submit that independent claims 1, 24, 35, 58 and 107 are allowable over Dugmore, Novosel and Peterson. Further, dependent claims 2, 4, 5, 9-23, 25, 27, 30-34, 36, 37, 39, 43-57, 59, 62 and 64-68 are submitted to be allowable over Dugmore, Novosel and Peterson in the same manner, because they are dependent on independent claims 1, 24, 35 and 58, respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 2, 4, 5, 9-23, 25, 27, 30-34, 36, 37, 39, 43-57, 59, 62 and 64-68 recite additional novel elements not shown by Dugmore, Novosel and Peterson.

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V. Conclusion

In view of the above, it is submitted that this application is now in good order for allowance and such allowance is respectfully solicited. Should the Examiner believe minor matters still remain that can be resolved in a telephone interview, the Examiner is urged to call Applicants' undersigned attorney.

Respectfully submitted,

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